

## Advancing clinical research with MHC I Dextramer® [GMP]

Immune monitoring by flow cytometry is an increasingly important element in clinical research, cell therapy - and vaccine development.

Immudex offers MHC I Dextramer® [GMP] for applications that require excellent quality reagents produced with a high level of documentation, such as:

- Components for laboratory-developed tests (LDT)
- Reagents for medical devices governed by CLIA, FDA, and IVDD
- Tools for clinical trials and investigations in accordance with GC[L]P
- Materials for manufacturing and quality control of investigational and commercial pharmaceutical products

Quality  
that meets  
Regulatory  
Requirements



## MHC I Dextramer® produced according to current good manufacturing practices [cGMP]

Immudex is ISO 13485:2016 certified, registered with the FDA and audited regularly, which guarantees that MHC I Dextramer® [GMP] are produced in compliance with strict international cGMP standards for medical devices regarding quality control and product traceability.

Every step of the manufacturing process described in our Quality Management System [QMS] includes:

- Documented procedures
- Documented employee training
- Material traceability
- Equipment maintenance and monitoring records
- In-process quality control
- Final product quality control
- Established shelf-life and expiry date
- Batch record review of released products
- Batch specific certificate of analysis
- Change notifications
- Supplier evaluation, including on-site audit – upon request

## Applications of MHC I Dextramer<sup>®</sup> (GMP) include:

- Analysis of patient samples from clinical trials
- Quality control of cell-based immunotherapies by flow cytometry
- Efficient and accurate quantification of antigen-specific T cells in patients receiving treatment with drugs or vaccines



Accurate data rely  
on biological assays  
made with high  
quality reagents

## Immudex can help you achieve your clinical goals

Immudex is renowned for its MHC multimers of the highest quality based on Dextramer<sup>®</sup> technology. We produce and sell a Dextramer<sup>®</sup> CMV Kit [IVD] designed to enumerate CMV-specific CD8<sup>+</sup> T cells in whole blood by flow cytometry.

With deep knowledge of immune monitoring by flow cytometry and more than 10 years of experience with manufacturing we have produced GMP Dextramer<sup>®</sup> with various different HLA alleles and peptide epitopes and offered advice on experimental design to numerous customers worldwide. Contact our customer support to discuss your projects and needs for GMP reagents.

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For research use only. Not for use in diagnostic or therapeutic procedures.